



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

VAN DEN BRINK et al

Atty. Ref.: 4560-4

Serial No. 10/518,414

TC/A.U.: 1636

Filed: August 30, 2005

Examiner: Joike, M.K.

For: IMPROVED METHOD OF PRODUCING AN ASPARTIC PROTEASE
IN A RECOMBINANT HOST ORGANISM

August 17, 2009

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

Appellants provide herein a response to aspects of the Examiner's Answer mailed June 17, 2009, for consideration by the Board in addition to Appellants' Appeal Brief filed February 13, 2009, and pursuant to 37 CFR § 41.41 and MPEP § 1208¹.

¹ The reply brief should include the following items, with each item starting on a separate page, so as to follow the other requirements of a brief as set forth in 37 CFR 41.37(c):
(A) Identification page setting forth the appellant's name(s), the application number, the filing date of the application, the title of the invention, the name of the examiner, the art unit of the examiner and the title of the paper (i.e., Reply Brief);
(B) Status of claims page(s);
(C) Grounds of rejection to be reviewed on appeal page(s); and
(D) Argument page(s).

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(I) STATUS OF CLAIMS

Claims 1-15 and 17-23 are pending. Claims 1-5, 8-15, 17-19, 22 and 23 have been finally rejected. Claims 6, 7, 20 and 21 stand objected to but are indicated as being allowable if rewritten in independent form. Claim 16 has been cancelled.

A copy of rejected claims 1-5, 8-15, 17-19, 22 and 23, that is, the claims involved in the appeal, is attached as a Claims Appendix to Appellants' Appeal Brief, pursuant to Rule 41.37(c)(1)(viii).

(II) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The following grounds of rejection are presented for review:

Whether claims 17-19 are anticipated under 35 USC 102(b) by USP 6,127,142.

Whether claims 1-5, 8, 12-15, 17-19 and 22 would have been obvious under 35 USC 103(a) over USP 5,800,849 in view of Kasturi et al (Biochem. J. 323:415-419 (1997)), and further in view of USP 6,127,142.

Whether claims 9-11 and 23 would have been obvious under 35 USC 103(a) over USP 5,800,849, Kasturi et al (Biochem. J. 323:415-419 (1997)), USP 6,127,142 and further in view of Korman et al (Curr. Genet. 17:203-212 (1990)).

(III) ARGUMENT

REJECTION OF CLAIMS 17-19 UNDER 35 USC 102(b) AS ANTICIPATED BY USP 6,127,142

The subject matter of claims 17-19 is not anticipated by USP 6,127,142. The rejection of claims 17-19 under 35 USC 102(b) should be reversed. Consideration of Appellants' Appeal Brief and the following in this regard are requested.

On page 9 of the Examiner's Answer, lines 10-14, the Examiner states:

Appellants argue that the reference teaches an aspartic protease that is not chymosin. However, they do not exclude chymosin. Appellant are citing EC 3.4.23.23 as the aspartic protease taught in US 6,127,142. This aspartic protease is taught in Ex. 1, which also reaches the enzyme, HannilaseTM, which is a member of the chymosin family.

Respectfully, this statement is not correct. HannilaseTM is not a member of the chymosin family. HannilaseTM is a *Rhizomucor* protease classified in EC 3.4.23.23. Chymosin is classified in EC 3.4.23.4.

Reversal of the 35 USC 102(b) rejection of claims 17-19 over USP 6,127,142 is requested for the reasons presented in the Appeal Brief of February 13, 2009, and as supplemented herein.

REJECTION OF CLAIMS 1-5, 8, 12-15, 17-19 AND 22 UNDER 35 USC 103(a) AS OBVIOUS OVER USP 5,800,849 IN VIEW OF KASTURI ET AL AND USP 6,127,142.

The subject matter of claims 1-5, 8, 12-15, 17-19 and 22 would not have been obvious over the combination of USP 5,800,849, Kasturi et al and USP 6,127,142. The

rejection of claims 1-5, 8, 12-15, 17-19 and 22 under 35 USC 103(a) should be reversed.

Consideration of Appellants' Appeal Brief and the following in this regard are requested.

On page 10 of the Examiner's Answer, lines 9 and 10, the Examiner states:

However, US 6,127,142 teaches the use of chymosin, and an NXT site present on a protease.

The Examiner contends on page 3 of the May 13, 2008 Office Action that the statement at column 6, lines 38-41 of USP 6,127,142 which reads as follows:

Thus, as an example, a suitable milk clotting enzyme should ideally have an activity ratio similar to or close to that of pure calf chymosin for milk clotting activity at two different pH values such as 6.0/6.5 or 6.5-7.0

implies that bovine chymosin is acceptable to use as the protease. This assertion, however, ignores the fact that USP 6,127,142 relates to a method of deglycosylating a protease that is not a chymosin. The statement quoted above does not alter that fact – the quoted passage merely indicates a target activity ratio for the deglycosylated *Rhizomucor miehei* aspartic protease. This is clear from the sentence that follows at column 6, lines 43-48 of USP 6,127,142 which reads as follows:

Thus, it was found during the experimentation leading to the present invention that treatment of certain *Rhizomucor miehei* aspartic proteases having a relatively high pH dependency (ie. activity ratios above that of chymosin) with Endo H reduced the pH 6.0/6.5 or the 6.5/7.0 activity ratios to values closer to that of calf chymosin.

In view of the above, it is submitted that USP 6,127,142 does not teach the use of chymosin.

Reversal of the 35 USC 103(a) rejection of claims 1-5, 8, 12-15, 17-19 and 22 over USP 5,800,849, Kasturi et al and USP 6,127,142 is requested for the reasons presented in the Appeal Brief of February 13, 2009, and as supplemented herein.

REJECTION OF CLAIMS 9-11 AND 23 UNDER 35 USC 103(a) AS OBVIOUS OVER USP 5,800,849, KASTURI ET AL, USP 6,127,142 AND KORMAN ET AL

The subject matter of claims 9-11 and 23 would not have been obvious over the combination of USP 5,800,849, Kasturi et al, USP 6,127,142 and Korman et al. The rejection of claims 9-11 and 23 under 35 USC 103(a) should be reversed. Consideration of Appellants' Appeal Brief and the following in this regard are requested.

For the reasons detailed above, the Examiner is in error in stating in the Examiner's Answer that USP 6,127,142 teaches the use of chymosin.

Reversal of the 35 USC 103(a) rejection of claims 9-11 and 23 over USP 5,800,849, Kasturi et al, USP 6,127,142 and Korman et al is requested for the reasons presented in the Appeal Brief of February 13, 2009, and as supplemented herein.

CONCLUSION

In conclusion, it is believed that the application is in clear condition for allowance; therefore, early reversal of the Final Rejection and passage of the subject application to issue are earnestly solicited.

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Respectfully submitted,

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